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 Filed : November 10, 2000

# AMENDMENTS TO THE CLAIMS

1. (cancelled)

2. (previously amended): A method for providing access to a series of adjacent vertebrae located within a human lumbar and sacral spine having an anterior aspect, a posterior aspect and an axial aspect, wherein the axial aspect is curved in the posterior-anterior plane due to curvature of the spinal column, the vertebrae separated by intact or damaged spinal discs, the method comprising the steps of:

accessing an anterior or posterior sacral target point of a sacral vertebra in alignment with a visualized, curved axial instrumentation/fusion line extending in said axial aspect through the series of adjacent vertebral bodies; and

from the accessed sacral target point, boring a <sup>plurality of diverging</sup> curved trans-sacral axial bore<sup>s</sup> in alignment with said axial instrumentation/fusion line cephalad and axially through the vertebral bodies of said series of adjacent vertebrae and any intervertebral spinal discs;

wherein the boring step further comprises the steps of:

providing a boring assembly comprising a boring head capable of being imaged at the distal end of a flexible boring drive shaft and a directional control mechanism for adjusting a boring angle of the boring head;

imaging the boring head and the vertebrae;

while observing the imaged boring head and vertebrae, advancing the boring head from the anterior or posterior target point through the vertebral bodies and any intervening discs; and

during advancement, adjusting the boring angle of the boring head to form a curve in the axial bore.

3. (original): The method of Claim 2, wherein the adjusting step further comprises the steps of:

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straightening the boring angle of the boring head when boring through opposed end faces of facing vertebral bodies and the intervening disc space so that the axial bore is aligned axially normal to the opposed end faces of the facing vertebral bodies; and

deflecting the boring angle of the boring head when boring within a vertebral body between the end faces of the vertebral body, whereby the curved axial bore can be formed of relatively straight and curved sections.

4. (previously amended): A method for providing access to a series of adjacent vertebrae located within a human lumbar and sacral spine having an anterior aspect, a posterior aspect and an axial aspect, wherein the axial aspect is curved in the posterior-anterior plane due to curvature of the spinal column, the vertebrae separated by intact or damaged spinal discs, the method comprising the steps of:

accessing an anterior or posterior sacral target point of a sacral vertebra in alignment with a visualized, curved axial instrumentation/fusion line extending in said axial aspect through the series of adjacent vertebral bodies; and

BI from the accessed sacral target point, boring a curved trans-sacral axial bore in alignment with said axial instrumentation/fusion line cephalad and axially through the vertebral bodies of said series of adjacent vertebrae and any intervertebral spinal discs;

Conf wherein the boring step further comprises the steps of:

providing a boring assembly comprising a boring drill bit capable of being imaged at the distal end of a flexible drive shaft, the drive shaft coupled at a drive shaft proximal end to a drill motor and at a drive shaft distal end to the drill bit, whereby the drill bit and drive shaft are rotatable by operation of the drill motor, a flexible inner sheath having an inner sheath lumen through which said drive shaft extends said inner sheath having a curved distal segment, and a straight flexible outer sheath having an outer sheath lumen through which said inner sheath extends, the outer and inner sheaths providing directional control to the boring angle of the drill bit by selectively distally advancing or proximally retracting the outer sheath over or from a distal segment of the inner sheath; and

operating the drill motor and advancing the drill bit from the anterior or posterior target point while adjusting the boring angle of the drill bit by selectively advancing or retracting the outer sheath over or from the distal segment of the inner sheath to drill the

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axial bore through the vertebral bodies and any intervening discs in alignment with the axial instrumentation/fusion line.

5. (original): The method of Claim 4, wherein the adjusting step further comprises the steps of:

straightening the boring angle of the drill bit when boring through opposed end faces of facing vertebral bodies and the intervening disc space by extending the outer sheath distally over the inner sheath so that the axial bore is aligned axially normal to the opposed end faces of the facing vertebral bodies by advancing the outer sheath distally over the drive shaft; and

deflecting the boring angle of the drill bit when boring within a vertebral body between the end faces of the vertebral body by retracting the outer sheath proximally over the inner sheath, whereby the curved axial bore can be formed of relatively straight and curved sections.

6 - 21 (cancelled)

22. (original): A method for providing access to a series of adjacent vertebrae located within a human lumbar and sacral spine having an anterior aspect, a posterior aspect and an axial aspect, wherein the axial aspect is curved in the posterior-anterior plane due to curvature of the spinal column, the vertebrae separated by intact or damaged spinal discs, the method comprising the steps of:

accessing an anterior or posterior sacral target point of a sacral vertebra in alignment with a visualized, curved axial instrumentation/fusion line extending in said axial aspect through the series of adjacent vertebral bodies; and

from the accessed sacral target point, boring a plurality of trans-sacral axial bores through the vertebral bodies of said series of adjacent vertebrae and any intervertebral spinal discs, the plurality of trans-sacral axial bores commencing in substantial axial alignment with said axial instrumentation/fusion line at the anterior or posterior sacral target point and extending in the cephalad direction axially through the vertebral bodies of said series of adjacent vertebrae and any intervertebral spinal discs, each trans-sacral axial bore diverging away from the axial instrumentation/fusion line and any other axial bore and terminating at spaced apart cephalad bore ends.

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23. (original): The method of Claim 22, wherein the boring step further comprises the steps of:

providing a boring assembly comprising a boring head capable of being imaged at the distal end of a flexible boring drive shaft of materials that are and a directional control mechanism for adjusting a boring angle of the boring head; and,  
in boring each of the plurality of trans-sacral axial bores:

imaging the boring head and the vertebrae;

while observing the imaged boring head and vertebrae, advancing the boring head from the anterior or posterior target point initially in alignment with the axial instrumentation/fusion line and then in the cephalad direction through the vertebral bodies and any intervening discs; and

during advancement, adjusting the boring angle of the boring head to bore the axial bore diverging away from the axial instrumentation/fusion line and any other axial bore of the plurality of diverging axial bores.

24. (original): The method of Claim 23, wherein the adjusting step further comprises the steps of:

straightening the boring angle of the boring head when boring through opposed end faces of facing vertebral bodies and the intervening disc space so that the axial bore is aligned axially normal to the opposed end faces of the facing vertebral bodies; and

deflecting the boring angle of the boring head when boring within a vertebral body between the end faces of the vertebral body, whereby the curved axial bore can be formed of relatively straight and curved sections.

25. (original): The method of Claim 22, wherein the boring step further comprises the steps of:

providing a boring assembly comprising a boring drill bit capable of being imaged at the distal end of a flexible drive shaft, the drive shaft coupled at a drive shaft proximal end to a drill motor and at a drive shaft distal end to the drill bit, whereby the drill bit and drive shaft are rotatable by operation of the drill motor, a flexible inner sheath having an inner sheath lumen

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through which said drive shaft extends said inner sheath having a curved distal segment, and a straight flexible outer sheath having an outer sheath lumen through which said inner sheath extends, the outer and inner sheaths providing directional control to the boring angle of the drill bit by selectively distally advancing or proximally retracting the outer sheath over or from a distal segment of the inner sheath; and

operating the drill motor and advancing the drill bit from the anterior or posterior target point while adjusting the boring angle of the drill bit by selectively advancing or retracting the outer sheath over or from the distal segment of the inner sheath to drill the diverging axial bore through the vertebral bodies and any intervening discs.

26. (original): The method of Claim 25, wherein the adjusting step further comprises the steps of:

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straightening the boring angle of the drill bit when boring through opposed end faces of facing vertebral bodies and the intervening disc space by extending the outer sheath distally over the inner sheath so that the axial bore is aligned axially normal to the opposed end faces of the facing vertebral bodies by advancing the outer sheath distally over the drive shaft; and

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deflecting the boring angle of the drill bit when boring within a vertebral body between the end faces of the vertebral body by retracting the outer sheath proximally over the inner sheath, whereby the curved axial bore can be formed of relatively straight and curved sections.

27. (withdrawn): The method of Claim 22, wherein the boring step further comprises the steps of:

providing a boring assembly comprising a boring drill bit capable of being imaged at the distal end of a flexible drive shaft, the drive shaft coupled at a drive shaft proximal end to a drill motor and at a drive shaft distal end to the drill bit, whereby the drill bit and drive shaft are rotatable by operation of the drill motor, a drive shaft sheath extending between a drive shaft sheath proximal end to a drive shaft sheath distal end and having a drive shaft sheath lumen through which said drive shaft extends, a tip deflection wire extending from a tip deflection wire distal end coupled with the drive shaft distal end to a tip deflection wire proximal end, the tip deflection wire providing directional control to the boring angle of the drill bit by selectively applying tension to or releasing tension from the tip deflection wire proximal end while

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advancing the drill bit to bore a curved axial bore visualized by observation of the imaged drill bit and vertebrae of the spine; and

operating the drill motor and advancing the drill bit and drive shaft from the anterior or posterior target point while adjusting the boring angle of the drill bit by selectively applying tension to or releasing tension from the tip deflection wire from the tip deflection wire proximal end to drill the diverging axial bore through the vertebral bodies and any intervening discs.

28. (withdrawn): The method of Claim 27, wherein the adjusting step further comprises the steps of:

releasing tension from the tip deflection wire to straighten the boring angle of the drill bit when boring through opposed end faces of facing vertebral bodies and the intervening disc space so that the axial bore is aligned axially normal to the opposed end faces of the facing vertebral bodies; and

applying tension to the tip deflection wire to deflect the boring angle of the drill bit when boring within a vertebral body between the end faces of the vertebral body, whereby the curved axial bore can be formed of relatively straight and curved sections.

29. (withdrawn): The method of Claim 22, wherein the boring step further comprises the steps of:

providing a boring assembly comprising a boring drill bit capable of being imaged at the distal end of a flexible drive shaft, the drive shaft coupled at a drive shaft proximal end to a drill motor and at a drive shaft distal end to the drill bit, whereby the drill bit and drive shaft are rotatable by operation of the drill motor, a flexible drive shaft sheath enclosing and extending along the drive shaft to a drive shaft sheath distal end, the drive shaft sheath having a sheath axis and a sheath lumen extending between the drive shaft sheath proximal and distal ends through which the drive shaft extends, the sheath lumen disposed off center from the sheath axis, whereby the drive shaft sheath provides directional control to the boring angle of the drill bit by selectively advancing the drive shaft sheath over a distal segment of the drive shaft to apply the drive shaft sheath distal end against a surface of the drill bit to urge the drill bit in the direction that the off center sheath lumen is from the sheath axis thereby imparting an offset boring angle

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to the drill bit or by retracting the drive shaft sheath from the distal segment of the drive shaft to enable the drive shaft section extended distally from the drive shaft sheath to straighten; and

operating the drill motor and advancing the drill bit and drive shaft and drive shaft sheath from the anterior or posterior target point while adjusting the boring angle of the drill bit by selectively advancing the drive shaft sheath or retracting the drive shaft sheath over or from the distal segment of the drive shaft to drill the diverging axial bore through the vertebral bodies and any intervening discs.

30. (withdrawn): The method of Claim 29, wherein the adjusting step further comprises the steps of:

retracting the drive shaft sheath proximally over the drive shaft to straighten the boring angle of the drill bit when boring through opposed end faces of facing vertebral bodies and the intervening disc space so that the axial bore is aligned axially normal to the opposed end faces of the facing vertebral bodies by; and

advancing the drive shaft sheath distally over the drive shaft to deflect the boring angle of the drill bit when boring within a vertebral body between the end faces of the vertebral body, whereby the curved axial bore can be formed of relatively straight and curved sections.

31 - <sup>42</sup>~~50~~ (cancelled)